DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference Nos.: 96-1367, 97-0501, 97-0522

January 9, 1998

Bernardita Mendez, Ph.D.
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916

Dear Dr. Mendez:

Your requests to supplement your biologics license application for Aldesleukin with the above referenced supplements have been approved. This approval includes a new indication for use in adults with metastatic melanoma and updated response data for metastatic renal cell carcinoma patients, as well as revised pharmacokinetics information, and adverse reactions, precautions and warning sections of the package insert.

We acknowledge your written commitments of January 7, 1998, including:

1. To obtain clinical data, including support of clinical studies, on the use of lower dose regimens of Aldesleukin as a single agent, in alternative regimens, and/or in combination with other chemotherapeutic agents. If the data demonstrate potential clinical benefit, or if the data are inconclusive, to undertake further studies. To submit the data which demonstrate significant clinical benefit as a supplement to the existing license.

2. To follow-up on those metastatic renal cell carcinoma and metastatic melanoma patients who have either responded to Aldesleukin therapy or who were alive at the last follow-up, at every two year intervals.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

This information will be included in your biologics license application file.

Sincerely yours,

Karen D Weiss MD

Karen D. Weiss, M.D.
Director
Division of Clinical Trial Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research